DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Eovist
Docket No.: FDA-2009-E-0020

JUL 15 2009

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,039,931, filed by Bayer Schering Pharma Aktiengesellschaft, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Eovist (gadoxetate disodium), the human drug product claimed by the patent.

The total length of the regulatory review period for Eovist (gadoxetate disodium) is 3,818 days. Of this time, 3,450 days occurred during the testing phase and 368 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 21, 1998.

   The applicant claims January 19, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 1998, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: July 2, 2007.

   The applicant claims June 29, 2007, as the date the new drug application (NDA) for Eovist (NDA 22-090) was initially submitted. However, FDA records indicate that NDA 22-090 was submitted on July 2, 2007.

3. The date the application was approved: July 3, 2008.

   FDA has verified the applicant's claim that NDA 22-090 was approved on July 3, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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